

Remarks

In the outstanding Official Action, the Examiner:

(1) acknowledged Applicant's election of a valve shield of Species A, Fig. 3; a fastener of Species A, sutures; and a sheet of material of Species B, a non-biological material;

(2) indicated that claims 7-11 and 13-17 are withdrawn from further consideration;

(3) objected to the disclosure because of informalities, and required correction; and

(4) rejected claims 1-6, 12 and 18 under 35 USC 102(b) as being clearly anticipated by Kusahara.

In response to Items 1 and 2 above, Applicant expressly reserves the right to prosecute all non-elected subject matter in related applications.

In response to Item 3 above, Applicant now has amended the specification as suggested by the Examiner so as to replace "Fig. 1" with -- Fig. 3 -- on page 6, line 21, replace "Fig. 2" with -- Fig. 4 -- on page 7, line 4, and replace "Fig. 1" with -- Fig. 3 -- on page 7, line 17. Accordingly, the specification is believed to be allowable.

In response to Item 4 above, Applicant has now amended claims 1, 3-5 and 18, and has now added new claim 19, so as to more clearly define the present invention as claimed with respect to Kusahara.

Independent claim 1 of the present invention comprises a valve shield comprising a shaped sheet of material adapted to be affixed to the annulus of a valve, the shaped sheet having a given surface area configured to match at least a portion of at least one leaflet of the valve, and the shaped sheet of material adapted to contact extend over the at least a portion of the at least one leaflet of the valve so as to assist or replace the closing function of that valve leaflet.

Applicant believes that Kusuhara discloses an occluder supporter having two stitched attachment portions configured for attachment to contralateral edges of the native occluder of a valve, and one or more supports connecting the two stitched attachment portions to one another. Applicant believes that Kusuhara discloses that the occluder supporter is disposed to transect the valve opening and to create a condition wherein the contralateral edges of the native occluder of the ventricular side of the ventricular valve of the heart valve are held in a mutually close position, and the stitched attachments are attached to the aforementioned contralateral edges in order to attach the occluder supporter to the native occluder of the atrium side of the ventricular valve. Applicant believes that Kusuhara does not disclose a valve shield comprising a shaped sheet of material having a given surface area configured to match at least a portion of at least one valve leaflet of the valve, the shaped sheet of material adapted to contact at least a portion of the at

least one leaflet of the valve so as to assist or replace the closing function of that valve leaflet. Accordingly, independent claim 1 is believed to be in condition for allowance.

Claims 2-6, 12 and 19, which depend either directly or ultimately from independent claim 1, are believed to be in condition for allowance for at least the above-identified reasons. Accordingly, allowance of claims 2-6, 12 and 19 is respectfully requested.

Independent claim 18 of the present invention comprises a method for reducing regurgitation in a valve having a plurality of leaflets, the method comprising providing a valve shield comprising a shaped sheet of material having a given surface area configured to match at least a portion of at least one leaflet of the valve, and the shaped sheet of material adapted to contact the at least a portion of the at least one leaflet of the valve, and affixing the valve shield to the annulus of the valve so that it contacts the at least a portion of at least one leaflet of the valve so as to assist or replace the closing function of that valve leaflet.

Applicants believe that Kusuhara as discussed hereinabove does not disclose neither (1) a valve shield comprising a shaped sheet of material having a given surface area configured to match at least a portion of at least one leaflet of the valve, and the shaped sheet of material adapted to contact the at least a portion of the at least one leaflet of the valve, nor (2) a

method of affixing such a valve shield to the annulus of a valve such that it contacts at least a portion of at least one leaflet of the valve. Accordingly, claim 18 is believed to be in condition for allowance, and allowance thereof is respectfully requested.

In the event that any additional fees may be required to be paid in connection with this submission, please charge the same, or credit any overpayment, to Deposit Account No. 16-0221.

Respectfully submitted,

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